

Claims

1. A bioabsorbable implantable stent having a tubular, radially compressible and self-expandable braided and annealed structure comprising:

5 a first set of between 5 and 18 filaments each of which extends in a helix configuration along a center line of the stent and having a first common direction of winding;

a second set of filaments of the same number as the first set, each of which extends in a helix configuration along a center line of the stent and having a second common direction of winding;

10 the second set of filaments crossing the first set of filaments at an axially directed angle of between about 120 and about 150 degrees when in a first free radially expanded state after being annealed but before being loaded on a delivery device so as to form a plurality of interstices between filaments;

15 each filament comprising PLLA, PDLA, PGA, or combinations thereof, and having a substantially solid and substantially uniform cross-section, a tensile strength of from about 40 ksi to about 120 ksi, a tensile modulus of from about 400,000 psi to about 2,000,000 psi, and an average diameter of from about 0.15 mm to about 0.6 mm;

20 wherein the first set of filaments and second set of filaments act upon one another to create an outwardly directed radial force sufficient to implant the stent in a body vessel upon deployment from a delivery device.

2. The stent of claim 1 wherein the stent has a second free radially expanded state after being loaded and then released from a deployment device, the first and second sets of filaments crossing at an axially directed angle of  
25 between about 80 and about 145 degrees when in the second free radially expanded state.

3. The stent of claim 1 wherein the stent has a second free radially expanded state after being loaded and then released from a deployment device, the first and second sets of filaments crossing at an axially directed angle of  
30 between about 90 and about 100 degrees when in the second free radially expanded state, and a second free state diameter of from about 3 mm to about 6 mm.

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4. The stent of claim 2 wherein the axially directed angle is between about 110 degrees and about 120 when in the second free radially expanded state.

5. The stent of claim 2 wherein the stent has an outside diameter when in the second free radially expanded state and the stent exerts an outwardly directed radial force at one half of the outside diameter of from about 40 grams to about 300 grams.

6. The stent of claim 2 wherein the stent has an implanted state after being loaded, released from a deployment device into a body vessel, and then implanted in the body vessel, with the first and second sets of filaments crossing at an axially directed angle of between about 95 and about 105 degrees when the stent is in the implanted state.

7. The bioabsorbable implantable stent of claim 1 wherein the stent is radially constrained to half of its free diameter and the radial force, RF, exerted by the device, in grams, as a function of annealed diameter, D, in mm, is about  $RF = -15D + 491 \pm 20$ .

8. The bioabsorbable implantable stent of claim 1 wherein the stent is annealed at a temperature of from about 60°C to about 180°C for a period of time of from about 5 minutes to about 120 minutes.

9. The bioabsorbable implantable stent of claim 1 wherein the stent is annealed at a temperature of from about 130°C to about 150°C for a period of time of from about 10 minutes to about 20 minutes.

10. The bioabsorbable implantable device of claim 1 wherein the stent is annealed to yield a crossing angle of from about 130 degrees to about 150 degrees.

11. The bioabsorbable implantable stent of claim 1 wherein the stent is further disposed in a stent delivery device and the filaments have a crossing angle of from about 30 degrees to about 120 degrees.

12. The bioabsorbable implantable stent of claim 1 wherein the stent is deployed from a delivery system into a body lumen and the filaments have a crossing angle of from about 70 degrees to about 130 degrees.

13. The bioabsorbable implantable stent of claim 1 wherein the stent provides structural integrity to a body lumen for less than about 3 years.

14. The bioabsorbable implantable stent device of claim 1 wherein the stent further comprises polydioxanone, polycaprolactone, polygluconate, polylactic acid-polyethylene oxide copolymers, modified cellulose, collagen, poly(hydroxybutyrate), polyanhydride, polyphosphoester, poly(amino acids) and combinations thereof.

15. The bioabsorbable implantable stent of claim 1 wherein the filaments are mono-filament or multi-filament.

16. The bioabsorbable implantable stent of claim 1 wherein the stent substantially degrades *in vivo* in from about 1 year to about 2 years.

17. The bioabsorbable implantable stent of claim 1 wherein the filaments comprise polyglycolide and whereby the stent substantially degrades *in vivo* in a time of from about 3 months to about 1 year.

18. The bioabsorbable implantable stent of claim 1 wherein the filaments further comprise polygluconate, polydioxanone, or combinations thereof and whereby the stent substantially degrades *in vivo* in from about 1 week to about 3 months.

19. The bioabsorbable implantable stent of claim 1 wherein the stent has at least one end of diminishing diameter so as to function as a filter.

20. The bioabsorbable implantable stent device of claim 1 wherein the filaments are substantially homogeneous in cross section and length.

21. The bioabsorbable implantable stent of claim 1 wherein the filaments have a tensile modulus of from about 400,000 psi to about 1,200,000 psi.

22. The bioabsorbable implantable stent of claim 1 wherein the filaments have a tensile modulus of from about 700,000 psi to about 1,200,000 psi.

23. The bioabsorbable implantable stent of claim 1 wherein the stent includes a plurality of the filaments helically wound and interwoven in a braided configuration to form a tube.

24. A method of using an implantable endoprosthesis comprising the steps of:

providing a tubular, radially compressible, axially flexible, and radially self-expandable braided and annealed structure comprising from about 10 to about 36 elongate filaments, the filament comprising PLLA, PDLA, PGA, and combinations thereof, each filament having a substantially uniform cross-section, a

tensile strength of from about 40 ksi to about 120 ksi, and a tensile modulus of from about 400,000 psi to about 2,000,000 psi, the filaments disposed at an angle of from about 130 degrees to about 150 degrees in a free state, each filament having an average diameter of from about 0.15 mm to about 0.6 mm, and the stent  
5 having a radial force at one-half diameter of from about 40 grams to about 300 grams, the annealed structure having a first diameter;

disposing the structure into a delivery system at a second diameter smaller than the first diameter;

inserting the delivery system and endoprosthesis in a body lumen;

10 deploying the endoprosthesis from the delivery system into the body lumen to a third diameter smaller than the first; and

allowing the endoprosthesis to self expand in the body lumen to a fourth diameter greater than the third diameter.

25. A method for treating a site within a vessel of a patient, including:

15 providing a biocompatible medical device comprised of a tubular and axially flexible braid-like annealed structure at a first diameter which is radially self-expandable between a compressed state and an expanded state and which includes from about 10 to about 36 elongate filaments wherein the filaments comprise PLLA, PDLA, PGA, and combinations thereof, each filament having a  
20 substantially uniform cross-section, a tensile strength of from about 40 ksi to about 120 ksi, and a tensile modulus of from about 400,000 psi to about 2,000,000 psi;

providing a delivery system with the medical device positioned on a portion of the delivery system in the compressed state at a second diameter smaller than the first diameter;

25 inserting the portion of the delivery system with the medical device into the patient's vessel at a location spaced from the treatment site, and manipulating the delivery system to advance the medical device through the vessel, to the treatment site;

30 deploying the medical device from the delivery system, the medical device being deployed at a third diameter smaller than the original free diameter and allowing the medical device to self-expand within the vessel; and

removing the delivery system from the patient with the medical device remaining in the expanded state and supporting the vessel.

26. A bioabsorbable implantable device made from the process comprising:

providing a plurality of elongate filaments comprising PLLA, PDLA, PGA, and combinations thereof;

5 braiding the filaments on a first mandrel of from about 3 mm to about 30 mm diameter at a braid angle of from about 120 degrees to about 150 degrees on to form a tubular, radially compressible, axially flexible, and radially self-expandable device, the device having a first diameter of from about 2 mm to about 10 mm larger than the final implanted device diameter; and

10 annealing the device on a second mandrel at a temperature between about the polymer glass-transition temperature and the melting temperature for a time period between about 5 and about 120 minutes, the second mandrel having a second diameter smaller than the first diameter, the second mandrel diameter adapted to be computed from a linear equation relating radial  
15 force to annealed stent diameter, the equation being derived from measured radial force and measured annealed stent diameter data from two stent prototypes made on two anneal mandrel diameters and deployed from a device delivery system.

27. The bioabsorbable implantable device made from the process of claim 26 wherein each filament has a substantially uniform cross-section, a tensile  
20 strength of from about 40 ksi to about 120 ksi, and a tensile modulus of from about 400,000 psi to about 2,000,000 psi.

28. The bioabsorbable implantable device made from the process of claim 26 wherein annealing causes the device to radially shrink.

29. A method of manufacturing a stent comprising:  
25 providing from about 10 to about 36 filaments consisting essentially of poly (alpha-hydroxy acid), the filaments having an average diameter from about 0.15 mm to about 0.60 mm;

braiding the filaments at a braid angle of from about 120 degrees to about 150 degrees on a braid mandrel of from about 3 mm to about 30 mm  
30 diameter ;

removing the braid from the braid mandrel;

disposing the braid on an annealing mandrel having an outer diameter of from about 0.2 mm to about 10 mm smaller than the braid mandrel diameter;

- 5     annealing the braid at a temperature between about the polymer glass-transition temperature and the melting temperature for a time period between about 5 and about 120 minutes; and
- allowing the stent to cool.